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CASE BP/G-32983A

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Jun. 29, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

VUKMIROVIC ET AL.

APPLICATION NO: 10/521,298

FILED: MAY 24, 2005

FOR: STABLE PHARMACEUTICAL COMPOSITION COMPRISING
ERYTHROPOEITIN

MS: Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

RESPONSE TO ELECTION/RESTRICTION REQUIREMENT

Sir:

This response is to the election/restriction requirement mailed on May 29, 2007 ("Requirement").

Election/Restriction Requirement

The Patent Office asserts that the present application contains claims directed to one or more species of the generic invention. According to the Patent Office, "[t]hese species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1." Requirement, page 2. The Patent Office identified three "species," "species of Poloxamer polyol," "species of Polyhydric alcohol" and "species of Isotonicifying agent," and has required the applicant to make a three-way election of a single species within each of the identified "species." *Id.* The Patent Office identified claims 1, 11, 15 and 19 as generic. Restriction, page 4.

The Patent Office asserts that there is "an examination and search burden of these patentably distinct species due to their mutually exclusive characteristics." Restriction, page 2. According to the Patent Office, "[t]he species require a different field of search ... ; and/or prior art applicable to one species would not likely be applicable to another species; and/or the

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species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph." *Id.*

The Patent Office states that "[t]he species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature," asserting that Rosenthal, et al., WO 2002/00171 discloses a composition of EPO with a pharmaceutically acceptable buffer, a poloxamer and a polyhydric alcohol. Restriction, page 4. According to the Patent Office, "the special technical feature of the instant invention is not a contribution over the prior art and hence the application lacks unity of invention." *Id.*

Election of Species with Traverse

Applicants hereby elect, with traverse, the species comprising Pluronic F68 as the poloxamer polyol, glycerol as the polyhydric alcohol, and NaCl as the isotonicifying agent. Claims 1-20 read on this species.

Grounds for Traversal

First, invocation of PCT Rule 13.1 in this case is inappropriate. While a national stage filing of a PCT application, this is a United States patent application for purposes of examination, and is governed by U.S. law and regulations. Therefore, the appropriate standards to apply are those under U.S. laws, regulations and procedures, not those of the PCT Rules.

Second, the Patent Office has failed to meet the substantive standard for an election requirement under U.S. law, regulation, and procedure. On their face, the claims relate to the same invention, i.e., a stable pharmaceutical composition of erythropoietin (EPO) comprising (a) a therapeutically effective amount of EPO, (b) a pharmaceutically acceptable pH buffering system, (c) a poloxamer polyol, and (d) a polyhydric alcohol. Although the Patent Office asserts that the claims relate to patentably distinct species, no effort has been made to support this assertion. As stated in the MPEP § 808.01,

The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.

Inventions can be shown to be patentably distinct by showing, for example, that the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect, or that the inventions do not overlap in scope, i.e., are mutually exclusive, or that the inventions as claimed are not obvious variants. *C.f.*, MPEP § 8.14.01. The foregoing must establish that the supposedly separate inventions have acquired a separate status in the art, in view of their separate classification or due to their recognized divergent subject matter. *C.f.*, MPEP form paragraphs 8.21.01 and 8.21.02. The Patent Office has entirely failed to establish any of the foregoing.

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Instead of making the required showing under US law and regulations, the Patent Office merely states without support that there would be "an examination and search burden for these patentably distinct inventions due to their mutually exclusive characteristics." Requirement, page 2. The Patent Office asserts that "[t]he species require a different field of search," but has not explained why this is so, nor even identified any such "different fields of search." The Patent Office asserts that "prior art applicable to one species would not likely be applicable to another species," but has not explained or defined how prior art applicable to one species may not be applicable another species (in fact, the Patent Office goes on to site a single prior art reference, WO 2002/00171, which is asserted to apply to *all* of the claims). The Patent Office asserts that "the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph," but has not identified even a single non-prior art issue that might apply to one species but not to another. The Patent Office instead improperly focuses its substantive arguments on the PCT standard for unity of invention, asserting that pharmaceutical formulations as recited in the claims are found in the prior art and that therefore "the instant invention is not a contribution over the prior art." Restriction, page 4. While such a fact pattern may have bearing on whether or not the claimed invention is anticipated or obvious over the prior art, it is not a proper basis for imposing an election requirement.

Conclusion

In view of the foregoing, the applicants submit that the election requirement is improperly made, and unsupported, and request that it be withdrawn.

Respectfully submitted,



Mark Bowditch
Attorney for Applicants
Reg. No. 40,315

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(609) 627-8550

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